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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/241,455	02/02/99	KRIVITSKI	N

QM12/0518
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EXAMINER
SZMAL, B

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 05/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicati n No.

09/241,455

Applicant(s)

KRIVITSKI, NIKOLAI M.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn et al in view of Tu et al.

Quinn et al discloses a multi-lumen, multi-parameter catheter and its method of use that has a blood property change port and an aperture for the introduction of a bolus into the blood stream, a downstream sensor, and the means for determining the blood flow rate from the signal generated from the sensor, a heat source for generating a local temperature gradient, the sensor and blood property change port are spaced sufficiently apart to mix the dilution bolus through the port and blood flow, introducing a blood property change upstream of the sensor and detecting the change in the blood property at the sensor, and calculating the blood flow from the change in blood property and passage of the change past the sensor, a temperature gradient generator, locating the blood property altering section within a vessel, locating the sensor downstream of the blood property altering section, a plurality of blood parameter sensors in the vessel, and the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

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See Column 1, lines 44-67; Column 2, lines 1-21; Column 3, lines 48-63; Column 4, lines 60-67; and Column 5, lines 1-7.

Quinn et al, however fails to disclose the use of a catheter having a stenosis reducing member in order to performs a vascular corrective procedure, inserting the catheter to the site of the stenosis, reducing the stenosis in the vessel, and performing angioplasty to reduce the stenosis in the vessel.

Tu et al discloses a rapid exchange stented balloon catheter that has ablation capabilities and its method of use, that has a catheter having a stenosis reducing member in order to performs a vascular corrective procedure, inserting the catheter to the site of the stenosis, reducing the stenosis in the the vessel, and performing angioplasty to reduce the stenosis in the vessel. See Column 1, lines 26-39; and Column 3, lines 9-22.

Since both Quinn et al and Tu et al disclose catheters that can be used in vascular corrective procedures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Quinn et al to include the use of an angioplasty and other corrective procedures, as per the teachings of Tu et al, in order to provide a device and method that would allow a cardiac surgeon to determine the blood flow at the site of the stenosis and perform the corrective procedure with the use of a single catheter instead of changing the catheters in order to perform the procedure. It also would have been obvious to have the ability to locate the sensor with respect to the vessel to minimize wall effects in order to provide an accurate measurement of the blood flow rate without the possibility of an erroneous

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measurement. It also would have been obvious to utilize the equation for determining the blood flow rate since it can be easily deduced that the volume of the introduced indicator and the area under the dilution curve is related to the blood flow rate. It also would have been obvious to introduce a second indicator bolus into the bloodstream after the stenosis reduction procedure, detecting the indicator bolus, and determining the second blood flow rate and correlating it to the first measured flow rate, since it would allow a cardiac surgeon to determine the effectiveness of the procedure and would also allow the surgeon to redo the stenosis corrective procedure if it was deemed that the first procedure was not effective. It also would have been obvious to have separate catheters to perform the corrective procedure and determine the blood flow since it would allow the surgeon to remove the blood flow sensor when the corrective procedure is underway and would also allow for the reinsertion of the sensor to the stenosis site once the procedure is completed in order to determine the second blood flow rate. It also would have been obvious to insert a catheter to a stenosis site that has a stenosis reducing member and the blood flow sensor since it would allow the surgeon to introduce a single catheter into the vessel and perform the procedure, which would also make the procedure less time consuming. It also would have been obvious to rotate the sensor with respect to the vessel to reduce wall effects from the vessel, since the rotation of the sensor away from the perceived vessel wall would allow the sensor to be in the direct blood flow rather than providing erroneous data when it is against the vessel wall. It also would have been obvious to have the sensor detect changes in electrical impedance or resistance since it is well known that certain chemicals and blood constituents

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affect electrical impedance and resistance, therefore if a sensor can detect these differences, the method of determining the blood flow can use other means other than sensing thermal properties.

Response to Arguments

3. Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737 and group fax number is (703) 308-0758.

BS

May 13, 2000


Max Hindenburg
Primary Examiner